

I. SUPPLEMENTAL REMARKS

A. Claim Rejections Under 35 U.S.C. § 103

In the Office Action, claims 1-20, 25, and 28-30 were rejected under 35 U.S.C. §103(a) as being unpatentable over the combined disclosures of Whitcomb (USPN 6,011,049) and Byrd et al (USPN 6,191,162).

Further to Applicants' remarks submitted in the March 29, 2006 Amendment regarding the above-referenced rejection in respect to Whitcomb, Applicants submit that Whitcomb fails to teach or suggest a controlled release oral dosage form which is suitable for providing once-a-day oral administration of metformin or pharmaceutically acceptable salt thereof and which provides a mean AUC_{0-24} as recited in claims 43 and 47. In fact, Whitcomb teaches away from once-a-day administration as demonstrated in column 4, lines 59-63, wherein the reference discusses the administered doses of metformin hydrochloride, and notes that "These can be given up to two times a day or more."

In addition, in the Examples, wherein Whitcomb exemplifies administration of the combinations of the active agents, there is no indication that metformin is in a controlled release form. Further in the study with metformin and troglitazone, Whitcomb indicates that 1000 mg metformin is administered in the study "BID" (twice a day), while 400 mg troglitazone is administered "QD" (once a day). See, e.g., col. 14, lines 21-24 of Whitcomb.

It is respectfully submitted that one of ordinary skill in the art would not be motivated to formulate a controlled release oral dosage form suitable for providing once-a-day oral administration of metformin or pharmaceutically acceptable salt thereof as recited in the present claims, in view of Whitcomb's description of the administration of metformin hydrochloride to be given up to two times a day or more, and Whitcomb's exemplification of the administration of 1000 mg on a twice a day basis.

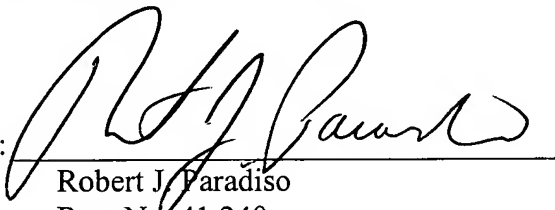
As Whitcomb fails to teach or suggest the presently claimed invention, the Examiner is respectfully requested to withdrawal this rejection.

II. CONCLUSION

In view of the amendments and arguments submitted in the March 29, 2005 Amendment, and the arguments presented above, it is believed that all claims are now in condition for allowance. An early and favorable action is earnestly solicited.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 
Robert J. Paradiso
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940